K020604

tyco Healthcare

Nellcor

APR 2 3 2002

4280 Hacienda Drive
Pleasanton, CA 94588

Tele: 925 463-4000
Fax: 925 463-4020

510(k) Summary

Submitted by:	Nellcor Puritan Bennett Incorporated (A business unit of Mallinckrodt Inc., a division of Tyco Healthcare Group LP) 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	Gina To Senior Regulatory Affairs Project Manager (925) 463-4427 (925) 463-4020 - FAX
Date Summary Prepared:	February 22, 2002
Trade Name:	WarmTouch Model 5300 Patient Warming System
Common/Usual Name:	Convective Air Warming System
Classification Name:	Thermal Regulating System per 21 CFR §870.5900
Product Code:	DWJ
Legally Marketed Predicate Device (Unmodified):	WarmTouch, Advanced Warming Systems, Inc., 510(k) #K913016

Device Description

The WarmTouch Model 5300 Patient Warming System surrounds the patient with warm air and convectively transfers heat across the skin. With the WarmTouch Model 5300 Patient Warming System, air is warmed and delivered into a lightweight blanket (*CareQuilt* or *CareDrape* Blanket) that rests over or under the patient.

The modification to the WarmTouch Patient Warming Unit consists of design changes relating to temperature settings.

Intended Use

The WarmTouch Model 5300 Patient Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia, for example, with the surgical patient, the patient in the pre-operative holding area, the pregnant woman who shivers during epidural anesthesia due to hypothermia, or any patient who is uncomfortable anywhere in the cold critical care environment.

Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device

The WarmTouch Model 5300 Patient Warming System has the same technological characteristics as the above referenced predicate device. The only changes relate to temperature settings.

Testing

Performance testing of the WarmTouch Model 5300 with the *CareQuilt* and *CareDrape* Blankets demonstrated safe maximum temperature compliance.

Testing of the WarmTouch Model 5300 Patient Warming System for electrical safety and EMC testing demonstrated compliance to applicable sections in the November 1993 FDA Review Guidance document, UL544 Standard for Safety for Medical and Dental Equipment, IEC 60601-1-2:1993 1st Edition requirements, IEC 60601-2-35 Particular Standard for Patient Warming Systems, and CAN/CSA C22.2 No. 125 for Electromedical Equipment. Performance testing demonstrated conformity to the draft ASTM Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices.

Conclusions

The WarmTouch Model 5300 Patient Warming System and the results of testing do not raise new questions of safety or effectiveness when compared to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2002

Ms. Gina To
Senior Regulatory Affairs Project Manager
Nellcor Puritan Bennett Incorporated
4280 Hacienda Drive
Pleasanton, CA 94588

Re: K020604
Trade Name: WarmTouch Model 5300 Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DNJ
Dated: March 27, 2002
Received: March 28, 2002

Dear Ms. To:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020604

Device Name: WarmTouch Model 5300 Patient Warming System

Indications For Use:

The WarmTouch Model 5300 Patient Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia, for example, with the surgical patient, the patient in the pre-operative holding area, the pregnant woman who shivers during epidural anesthesia due to hypothermia, or any patient who is uncomfortable anywhere in the cold critical care environment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020604

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)